

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA
WHEELING DIVISION

STATE OF WEST VIRGINIA, *ex rel.*
DARRELL V. MCGRAW, JR.,
ATTORNEY GENERAL,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB
COMPANY; SANOFI-AVENTIS U.S.,
LLC; SANOFI U.S. SERVICES, INC.;
and SANOFI-SYNTHELABO, INC.,

Defendants.

Case No. 5:13-cv-00013-IMK

DEFENDANTS' AMENDED ANSWER TO PLAINTIFF'S COMPLAINT
AND JURY DEMAND

Defendants Bristol-Myers Squibb Company ("BMS"), Sanofi-Aventis U.S. LLC, Sanofi-US Services Inc., and Sanofi-Synthelabo Inc.,¹ by and through undersigned counsel, hereby answer Plaintiff's Complaint (the "Complaint").

Plaintiff's Complaint consists largely of sweeping, conclusory allegations about Defendants' conduct without factual allegations supporting those averments. Accordingly, Defendants offer their responses herein without prejudice to their right to seek relief from the Court based on Plaintiff's failure to state a claim upon which relief can be granted and/or Plaintiff's failure to satisfy applicable pleading standards.

As to each allegation, Defendants respond as follows. All allegations are denied unless specifically admitted.

1. To the extent the allegations of Paragraph 1 are intended to summarize the allegations set forth in Plaintiff's Complaint, the allegations are improper and require no response. To the extent a response is deemed necessary, Defendants admit that Plaintiff brings this suit and seeks the relief requested, but deny that Plaintiff is entitled to any relief against Defendants whatsoever. Defendants deny the remaining allegations in Paragraph 1.

2. To the extent the allegations of Paragraph 2 are intended to characterize Plaintiff's claims, the allegations are improper and require no response. To the extent a response is deemed necessary, Defendants admit that Plaintiff brings this suit and seeks the relief requested, but deny that Plaintiff is entitled to any relief against Defendants whatsoever. Defendants deny the remaining allegations in Paragraph 2.

Parties

3. Answering the allegations of Paragraph 3, Defendants admit that the Attorney General of the State of West Virginia purports to bring this case on behalf of the State of West Virginia. Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 3 and therefore deny the same.

4. Answering the allegations of Paragraph 4, Defendants admit that BMS is a Delaware pharmaceutical company that maintains its headquarters at 345 Park Avenue, New York, New York 10154. Defendants further state that BMS is authorized to conduct business in

Footnote continued from previous page

¹ Sanofi-Aventis U.S. LLC was incorrectly designated "Sanofi-Aventis U.S., LLC," Sanofi US Services Inc. was incorrectly designated "Sanofi U.S. Services, Inc.," and Sanofi-Synthelabo Inc. was incorrectly designated "Sanofi-Synthelabo, Inc." in the Complaint.

West Virginia and its registered agent for service of process in West Virginia is CT Corporation System, 5400 D Big Tyler Road, Charleston, West Virginia 25313. Defendants deny the remaining allegations in Paragraph 4.

5. Defendants deny the allegations in Paragraph 5.

6. Answering the allegations of Paragraph 6, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was and has been responsible for manufacturing and marketing the prescription drug Plavix® in, among other places, the United States. Defendants deny the remaining allegations in Paragraph 6.

7. Answering the allegations of Paragraph 7, Defendants admit that Sanofi-Aventis U.S. LLC is a Delaware limited liability company that maintains its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendants further state that Sanofi-Aventis U.S. LLC is authorized to conduct business in West Virginia and its registered agent for service of process in West Virginia is Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302. Defendants deny the remaining allegations in Paragraph 7.

8. Answering the allegations of Paragraph 8, Defendants admit that Sanofi US Services Inc. is a Delaware corporation that maintains its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendants further state that Sanofi US Services Inc. is authorized to conduct business in West Virginia and its registered agent for service of process in West Virginia is Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302. Defendants deny the remaining allegations in Paragraph 8.

9. Answering the allegations of Paragraph 9, Defendants admit that Sanofi-Synthelabo Inc. is a Delaware corporation that maintains its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendants deny the remaining allegations in Paragraph 9.

10. The allegations of Paragraph 10 require no response.

11. Answering the allegations of Paragraph 11, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was and has been responsible for manufacturing and marketing the prescription drug Plavix® in, among other places, the United States. Defendants deny the remaining allegations in Paragraph 11.

12. Defendants deny the allegations in Paragraph 12.

13. To the extent Paragraph 13 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 13.

Jurisdiction and Venue

14. The allegations in Paragraph 14 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

15. The allegations in Paragraph 15 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

16. The allegations in Paragraph 16 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

17. The allegations in Paragraph 17 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

Factual Allegations

18. Answering the allegations of Paragraph 18, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was and has been responsible for manufacturing, testing, promoting, marketing, distributing, labeling, and selling the prescription drug Plavix® (clopidogrel bisulfate) in, among other places, the United States. Defendants

further state that on November 17, 1997, the U.S. Food and Drug Administration (“FDA”) approved Plavix® for sale in the United States for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease. Defendants further state that on February 27, 2002, FDA approved Plavix® for patients with unstable angina/non-Q-wave myocardial infarction, a type of acute coronary syndrome. Defendants further state that on August 17, 2006, FDA approved Plavix® for patients with ST-segment elevation acute myocardial infarction, another type of acute coronary syndrome. Defendants deny the remaining allegations in Paragraph 18.

19. Defendants deny the allegations in Paragraph 19.

20. Answering the allegations of Paragraph 20, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was and has been responsible for manufacturing, testing, promoting, marketing, distributing, labeling, and selling the prescription drug Plavix® (clopidogrel bisulfate) in, among other places, the United States. Defendants deny the remaining allegations in Paragraph 20.

21. Defendants deny the allegations in Paragraph 21.

22. To the extent Paragraph 22 alleges the approximate cost of aspirin, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 22 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. To the extent Paragraph 22 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to

the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 22.

23. To the extent Paragraph 23 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 23.

24. Defendants deny the allegations in Paragraph 24.

25. Defendants deny the allegations in Paragraph 25.

26. Answering the allegations of Paragraph 26, Defendants state that Plavix® was and has been marketed to both medical professionals and consumers, and that the Plavix® marketing material content speaks for itself. To the extent Paragraph 26 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 26.

27. To the extent Paragraph 27 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 27.

28. Defendants deny the allegations in Paragraph 28.

29. Defendants deny the allegations in Paragraph 29.

30. Defendants deny the allegations in Paragraph 30.

31. To the extent Paragraph 31 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 31.

32. Defendants deny the allegations in Paragraph 32.

33. Defendants deny the allegations in Paragraph 33.

34. Defendants deny the allegations in Paragraph 34.

35. Answering the allegations of Paragraph 35, Defendants state that FDA has approved Plavix® for sale in the United States for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, among other conditions. Defendants further state that the CAPRIE (Clopidogrel Versus Aspirin in Patients at Risk of Ischemic Events) Study was conducted and reported in *The Lancet* in 1996, and that this study and its design and results speak for themselves. Defendants deny the remaining allegations in Paragraph 35.

36. Answering the allegations of Paragraph 36, Defendants state that the CAPRIE (Clopidogrel Versus Aspirin in Patients at Risk of Ischemic Events) Study was conducted and reported in *The Lancet*, and that this study and its results speak for themselves. Defendants deny the remaining allegations in Paragraph 36.

37. Answering the allegations of Paragraph 37, Defendants state that the CAPRIE (Clopidogrel Versus Aspirin in Patients at Risk of Ischemic Events) Study was conducted and reported in *The Lancet*, and that this study and its results speak for themselves. Defendants deny the remaining allegations in Paragraph 37.

38. Answering the allegations of Paragraph 38, Defendants state that their sales training and marketing materials speak for themselves. To the extent Paragraph 38 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 38.

39. Answering the allegations of Paragraph 39, Defendants state that the Plavix® marketing material content speaks for itself. To the extent Paragraph 39 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 39.

40. Answering the allegations of Paragraph 40, Defendants state that the CHARISMA (Clopidogrel and Aspirin Versus Aspirin Alone for the Prevention of Atherothrombotic Events) Study was conducted and reported in *The New England Journal of Medicine* in 2006, and that this study and its results speak for themselves. Defendants deny the remaining allegations in Paragraph 40.

41. Answering the allegations of Paragraph 41, Defendants state that the report in question speaks for itself. Defendants deny the remaining allegations in Paragraph 41.

42. Answering the allegations of Paragraph 42, Defendants state that the PROfESS (Prevention Regimen for Effectively Avoiding Second Strokes) Study and its results speak for themselves. Defendants deny the remaining allegations in Paragraph 42.

43. Answering the allegations of Paragraph 43, Defendants state that the PROfESS Study and its results, and any publication by the American Stroke Association, speak for themselves. Defendants deny the remaining allegations in Paragraph 43.

44. Answering the allegations of Paragraph 44, Defendants state that their sales training materials, and any publication by the American Stroke Association, speak for themselves. Defendants deny the remaining allegations in Paragraph 44.

45. Defendants deny the allegations in Paragraph 45.

46. Defendants deny the allegations in Paragraph 46.

47. Defendants deny the allegations in Paragraph 47.

48. To the extent Paragraph 48 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 48.

49. Answering the allegations of Paragraph 49, Defendants state that any publication by the American Stroke Association speaks for itself. To the extent Paragraph 49 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 49.

50. Answering the allegations of Paragraph 50, Defendants state that any publication by the American Stroke Association speaks for itself. To the extent Paragraph 50 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 50.

51. Answering the allegations of Paragraph 51, Defendants state that any publication by the American Stroke Association speaks for itself. To the extent Paragraph 51 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 51.

52. Defendants deny the allegations in Paragraph 52.

53. Defendants deny the allegations in Paragraph 53.

54. Defendants deny the allegations in Paragraph 54.

55. Defendants deny the allegations in Paragraph 55.

56. To the extent the allegations of Paragraph 56 are intended to summarize the allegations set forth in Plaintiff's Complaint, the allegations are improper and require no response. To the extent a response is deemed necessary, Defendants deny the same. To the extent Paragraph 56 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 56.

57. Answering the allegations of Paragraph 57, Defendants repeat and incorporate by reference their response to all preceding paragraphs of this Answer as if fully set forth herein.

COUNT I

Violation of the West Virginia Consumer Credit and Protection Act

58. Answering the allegations of Paragraph 58, Defendants state that the West Virginia Code speaks for itself. Defendants deny the remaining allegations in Paragraph 58.

59. Answering the allegations of Paragraph 59, Defendants state that the West Virginia Code speaks for itself. Defendants deny the remaining allegations in Paragraph 59.

60. The allegations in Paragraph 60 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

61. Answering the allegations of Paragraph 61, including all subparts thereof, Defendants state that the West Virginia Code speaks for itself. Defendants deny the remaining allegations in Paragraph 61.

62. Defendants deny the allegations in Paragraph 62.

63. Defendants deny the allegations in Paragraph 63.

64. Defendants deny the allegations in Paragraph 64.

65. Defendants deny the allegations in Paragraph 65.

66. Defendants deny the allegations in Paragraph 66.

67. To the extent the allegations of Paragraph 67 are intended to summarize the allegations set forth in Plaintiff's Complaint, the allegations are improper and require no response. To the extent a response is deemed necessary, Defendants admit that Plaintiff brings this suit and seeks the relief requested, but deny that Plaintiff is entitled to any relief against Defendants whatsoever. Defendants deny the remaining allegations in Paragraph 67.

COUNT II

Misrepresentations to the Public Employees Insurance Agency

68. Answering the allegations of Paragraph 68, Defendants state that the West Virginia Code speaks for itself. Defendants deny the remaining allegations in Paragraph 68.

69. To the extent Paragraph 69 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 69.

70. Defendants deny the allegations in Paragraph 70.

71. Defendants deny the allegations in Paragraph 71.

72. Defendants deny the allegations in Paragraph 72.

COUNT III

Violation of the Insurance Fraud Prevention Act

73. Answering the allegations of Paragraph 73, Defendants state that the West Virginia Code speaks for itself. Defendants deny the remaining allegations in Paragraph 73.

74. To the extent Paragraph 74 alleges of what Plaintiff is informed or believes, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 74.

75. Defendants deny the allegations in Paragraph 75.

76. Defendants deny the allegations in Paragraph 76.

COUNT IV

Unjust Enrichment

77. Defendants deny the allegations in Paragraph 77.

78. Defendants deny the allegations in Paragraph 78.

79. Defendants deny the allegations in Paragraph 79.

80. Defendants deny the allegations in Paragraph 80.

81. Defendants deny the allegations in Paragraph 81.

82. Defendants deny the allegations in Paragraph 82.

COUNT V

Fraud and Negligent Misrepresentation

83. Defendants deny the allegations in Paragraph 83.

84. Defendants deny the allegations in Paragraph 84.

85. Defendants deny the allegations in Paragraph 85.

86. Defendants deny the allegations in Paragraph 86.

87. Defendants deny the allegations in Paragraph 87.

88. Defendants deny the allegations in Paragraph 88.

89. Defendants deny the allegations in Paragraph 89.

90. To the extent Paragraph 90 alleges upon what the State of West Virginia, prescribers, and PEIA participants and/or beneficiaries relied, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 90.

- 91. Defendants deny the allegations in Paragraph 91.
- 92. Defendants deny the allegations in Paragraph 92.
- 93. Defendants deny the allegations in Paragraph 93.
- 94. Defendants deny the allegations in Paragraph 94.
- 95. Defendants deny the allegations in Paragraph 95.

Punitive Damages

- 96. Defendants deny the allegations in Paragraph 96.
- 97. Defendants deny the allegations in Paragraph 97.

Answering the Paragraphs set forth under the unnumbered “WHEREFORE” paragraph, Defendants admit that Plaintiff seeks the relief requested but deny that Plaintiff is entitled to any relief against Defendants whatsoever.

AFFIRMATIVE DEFENSES²

FIRST AFFIRMATIVE DEFENSE

Plaintiff’s Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief on its common law claims because the Attorney General has no statutory authority to bring common law claims on behalf of the State of West Virginia.

THIRD AFFIRMATIVE DEFENSE

One or more of the claims set forth in Plaintiff’s Complaint are barred in whole or in part by the applicable statutes of limitation and/or statutes of repose.

² Defendants assert the following affirmative defenses without admitting or conceding that all of the affirmative defenses listed below are affirmative defenses for which they carry the burden of proof.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the sophisticated user doctrine.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted by federal law in that Plavix® was researched, tested, developed, manufactured, labeled, marketed, and sold in a manner consistent with the state of the art at the relevant time and approved by FDA.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comment k of Section 402A of the Restatement (Second) of Torts, and/or by the Restatement (Third) of Torts.

SEVENTH AFFIRMATIVE DEFENSE

Defendants plead collateral estoppel, res judicata, waiver, and laches.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation, if any, were caused in whole or part by Plaintiff's failure to exercise reasonable care and diligence to mitigate the alleged damage and/or by individual patients' failure to exercise reasonable care and diligence to mitigate their alleged damage.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable provisions of the U.S. Constitution, the West Virginia Constitution, and/or the applicable Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. These provisions include, but are not limited to, the First Amendment to the U.S.

Constitution and Article III, Section 7 of the West Virginia Constitution because Defendants' commercial speech regarding Plavix® was neither false nor misleading.

TENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff purports to seek equitable relief to mandate the specific content of Defendants' product labels, including their marketing and promotional material, Plaintiff's Complaint violates Defendants' right to freedom of speech under the First Amendment of the United States Constitution and the West Virginia Constitution, Article III, Section 7.

ELEVENTH AFFIRMATIVE DEFENSE

Defendants' conduct in all activities with respect to Plavix® has been and is under the supervision of FDA. Accordingly, this action is barred by the doctrine of primary jurisdiction.

TWELFTH AFFIRMATIVE DEFENSE

To the extent Plaintiff seeks equitable relief, such claims are barred because of mootness and/or because Plaintiff has an adequate remedy at law.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's alleged damages or losses were caused or contributed to be caused by the intervening acts, superseding negligence, and/or subsequent conduct or fault on the part of a person or entity over whom Defendants neither had control nor right of control and, therefore, Plaintiff's claims are barred and/or Defendants are entitled to an apportionment of damages accordingly.

FOURTEENTH AFFIRMATIVE DEFENSE

Any third party engaging in the acts alleged by Plaintiff was not acting as Defendants' agent or servant, at the instruction of Defendants, or within Defendants' control. Therefore,

Plaintiff's claims, to the extent they seek to recover for the acts or omission of such third parties, are barred in whole or in part as a matter of law.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims should be dismissed due to improper venue and/or pursuant to the doctrine of *forum non conveniens*.

SIXTEENTH AFFIRMATIVE DEFENSE

Defendants' activities and conduct conformed to all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time.

SEVENTEENTH AFFIRMATIVE DEFENSE

The alleged negligent or culpable conduct of Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's or alleged damages or losses.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because the use of the product at issue was generally recognized as safe and effective pursuant to conditions established by FDA and applicable regulations, including packaging and labeling regulations.

NINETEENTH AFFIRMATIVE DEFENSE

None of the factors set forth under West Virginia law governing punitive damages is present, and Plaintiff thus is not entitled to punitive damages.

TWENTIETH AFFIRMATIVE DEFENSE

None of Defendants' acts, conduct, omissions, or statements alleged in the Complaint was likely to mislead.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the prescribing physicians knew, at all times, the characteristics, uses, benefits, standard, and quality of the product at issue and therefore could not have justifiably relied on the alleged misrepresentations or omissions in the Complaint.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief under the statutes and legal theories invoked in the Complaint because Plaintiff lacks standing.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Defendants rely upon all defenses contained in any applicable state statute or law.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief on its claim of violation of the West Virginia Consumer Credit and Protection Act (the "CCPA") because the CCPA does not apply to the marketing, sale, and reimbursement of prescription drugs.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief on its claim of violation of the CCPA because the Attorney General failed to issue a pre-suit demand, as required by W. Va. Code § 46A-7-111(1).

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief on its claim of misrepresentation to the Public Employees Insurance Agency (the "PEIA") because the Attorney General is not statutorily authorized to bring claims on behalf of the PEIA.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief on its claim of violation of the Insurance Fraud Prevention Act (the “IFPA”) because the Attorney General is not statutorily authorized to bring claims under the IFPA.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff’s prayer for relief in the form of restitution and/or disgorgement is barred, in whole or in part, because Defendants did not retain any money belonging to Plaintiff as a result of any alleged excess charges.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff’s claims are barred, in whole or in part, by the voluntary payment doctrine.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiff’s claims are barred, in whole or in part, by its failure to exhaust administrative remedies.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Defendants state that West Virginia should reverse its present position regarding the learned intermediary doctrine, which doctrine would bar Plaintiff’s claims in whole or in part.

THIRTY-SECOND AFFIRMATIVE DEFENSE

To the extent Plaintiff’s claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to *Buckman v. Plaintiff’s Legal Committee*, 531 U.S. 341 (2001).

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff was aware of the alleged risks and nevertheless chose to reimburse or pay for Plavix®.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has failed to join indispensable parties and has improperly cumulated the claims of many patients on whose behalf Plaintiff is bringing this suit.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because they are speculative and remote and because of the impossibility of ascertaining and allocating the damages alleged.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

The utilization of private counsel in this action is improper because, upon information and belief, the compensation for the Special Assistant Attorneys General was not appropriated by the Legislature, as mandated by the West Virginia Constitution, Article VII, Section 19. Consequently, the utilization of private counsel, designated as Special Assistant Attorneys General, by the Attorney General to litigate the State's CCPA claim is in violation of the separation of powers doctrine. *See* W. Va. Const. Art. V, § 1.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

The utilization of private counsel, designated as Special Assistant Attorneys General, by the Attorney General to litigate the State's CCPA claim is a violation of Defendants' due process rights, pursuant to the U.S. Constitution, Amendment XIV, Section 1 and the West Virginia Constitution, Article III, Section 10.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

The utilization of private counsel, designated as Special Assistant Attorneys General, by the Attorney General to litigate the State's CCPA claim is an improper extension of the Attorney General's constitutional and statutory authority, including pursuant to the West Virginia Constitution, Article VII, Section 19 and W. Va. Code § 46A-7-102(1)(f). Specifically, the

utilization of private counsel to litigate this action on behalf of the State is improper because W. Va. Code § 46A-7-102(1)(f) mandates that the Attorney General may utilize only “qualified personnel *in his office*” to litigate CCPA claims on behalf of the State. *See* W. Va. Code § 46A-7-102(1)(f) (emphasis added).

THIRTY-NINTH AFFIRMATIVE DEFENSE

The utilization of private counsel, designated as Special Assistant Attorneys General, by the Attorney General to litigate the State’s CCPA claim is an improper extension of the Attorney General’s constitutional and statutory authority, including pursuant to the West Virginia Constitution, Article VII, Section 19 and W. Va. Code § 5-3-3 because W. Va. Code § 5-3-3 does not provide the Attorney General with the authority to appoint Special Assistant Attorneys General as contemplated in this action.

FORTIETH AFFIRMATIVE DEFENSE

West Virginia state agencies for whom Plaintiff is seeking recovery had full knowledge of, accepted, and assumed all risks and possible adverse effects related to the use of Plavix®. Defendants had no duty to warn. For these reasons, any recovery against Defendants is barred, in whole or in part, or offset under the principles of assumption of risk or comparative assumption of risk.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff has failed to plead causes of action for fraud and misrepresentation with sufficient particularity pursuant to W. Va. R. Civ. P. 9(b).

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff’s tort claims are barred by the economic loss doctrine and/or the doctrine of remoteness.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred as Defendants are neither in the business of insurance nor did they make a claim for insurance benefits or payment pursuant to an insurance policy.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Defendants' acts were at all times done in good faith and without malice, with respect to each and every purported cause of action in the Complaint.

FORTY-FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff requests punitive damages, penalties, or fines, such claims violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the U.S. Constitution, and corresponding portions of the Constitution of any State or Commonwealth of the United States whose laws might be deemed controlling in this case, on grounds including the following:

- a. It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the U.S. Constitution to impose punitive damages, penalties, or fines, which are penal in nature, against a civil defendant upon the Plaintiff satisfying a burden of proof that is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- b. The procedures pursuant to which punitive damages, penalties, or fines are awarded fail to provide a reasonable limit on the amount of the award of punitive damages, penalties, or fines, which thereby violates the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution;
- c. The procedures pursuant to which punitive damages, penalties, or fines are awarded fail to provide specific standards for the amount of the award of punitive damages,

penalties, or fines, which thereby violates the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution;

d. The procedures pursuant to which punitive damages, penalties, or fines are awarded result in the imposition of different penalties for the same or similar acts and thus violate the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution;

e. The procedures pursuant to which punitive damages, penalties, or fines are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution;

f. The procedures pursuant to which punitive damages, penalties, or fines are awarded permit the imposition of excessive fines in violation of the Eighth Amendment to the U.S. Constitution;

g. The award of punitive damages, penalties, or fines to Plaintiff in this action would constitute a deprivation of property without due process of law; and

h. The procedures pursuant to which punitive damages, penalties, or fines are awarded permit the imposition of an excessive fine and penalty.

FORTY-SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff requests punitive or exemplary damages and in the case of civil penalties or fines, Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards, including but not limited to, those standards of limitation that arose in *BMW of North America v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001),

State Farm Mutual Automobile Insurance Co. v. Campbell, 538 U.S. 408 (2003), and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

FORTY-SEVENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages and in the case of civil penalties or fines, an award of punitive damages or civil penalties or fines under the substantive law of the State of West Virginia violates the due process, equal protection, and excessive fines clauses of the U.S. Constitution and the West Virginia Constitution, including, but not limited to, Article III, Sections 5 and 10 of the West Virginia Constitution and the Eighth and Fourteenth Amendments to the U.S. Constitution.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages and in the case of civil penalties or fines, no act or omission of Defendants was malicious, knowing, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages or civil penalties or fines is barred. Additionally, because of the lack of clear standards, the imposition of punitive damages or civil penalties or fines against Defendants is unconstitutionally vague and/or overly broad.

FORTY-NINTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages and in the case of civil penalties or fines, Plaintiff's claim for punitive damages or civil penalties or fines must be limited by Defendants' relevant economic activity in the State of West Virginia.

FIFTIETH AFFIRMATIVE DEFENSE

Defendants hereby give notice that they intend to rely upon any other defense that may become available or appear during the discovery proceedings in the case and hereby reserve the right to amend this Answer to assert any such defense. Defendants also reserve the right to assert

other and related defenses as may become available upon a determination of the law applicable to the action or any part thereof or claim therein.

FIFTY-FIRST AFFIRMATIVE DEFENSE

This litigation is improper because, on information and belief, the magnitude of the penalties sought in this matter renders this an improper criminal prosecution pursuant to *State ex rel. Palumbo v. Graley's Body Shop, Inc.*, 188 W. Va. 501, 425 S.E.2d 177 (1992) and *Manchin v. Browning*, 170 W. Va. 779, 787, 296 S.E.2d 909, 917 (1982).

WHEREFORE, Defendants, having fully answered Plaintiff's Complaint, pray that Plaintiff takes nothing by this suit and demand as follows:

1. That Plaintiff's Complaint be dismissed with prejudice on the merits;
2. That Defendants recover their costs and disbursements herein expended to the extent permitted under applicable law;
3. That Defendants be granted leave to file an amended pleading upon conclusion of reasonable discovery, if necessary; and
4. That Defendants be accorded all other relief to which they now or hereafter appear to be entitled.

JURY DEMAND

Defendants hereby demand a jury trial on all issues so triable.

Dated: February 28, 2013

By: /s/ Michael J. Farrell

Michael J. Farrell (WVSB # 1169)

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SERVICES INC., AND SANOFI-
SYNTHELABO INC.

CERTIFICATE OF SERVICE

I hereby certify that, on February 28, 2013, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all known counsel of record who are participants.

/s/ Michael J. Farrell

Michael J. Farrell